Nemtabrutinib

We are currently accepting proposals for the Nemtabrutinib Investigator Initiated Studies Program (IISP). Please be aware that this is a highly competitive process.

To help to prepare a successful proposal, we are providing the following guidance:

- Please contact your local Regional Medical Scientific Director (RMSD, US only) or country specific liaison for any guidance pertaining to your specific concept prior to its submission, to ensure that it falls within the scope and interest of the Investigator Initiated Studies Program (IISP).
- Carefully review the Areas of Interest (AOI) below. Proposals that are not within the scope of these AOIs may be rejected without further review. Occasionally, we receive proposals out of the AOIs that represent "out of the box" thinking and are ultimately of great interest. If you believe this may apply for your proposal, please review with your RMSD or appropriate liaison prior to submission.
- Please include documentary evidence of successful and timely accrual and publication of investigators' studies in similar indications where possible. Feasibility is carefully considered in our assessment process.
- Pembrolizumab may be available for combination with Nemtabrutinib provided there is a strong rationale for the combination.
- Combinations with non-MSD agents may be considered. In such cases, it is the responsibility of the investigator to procure approval for supply of third-party agents, which should be demonstrated with a letter of support.
- The Program encourages less experienced investigators to seek guidance from a mentor prior to submitting IISP proposals. If working with a mentor please also provide their CV where possible, along with a detailed letter from the mentor describing the mentoring plan.
- Proposals with safety as a sole primary endpoint are out of scope.
- Proposals for which the primary objectives are translational should be directed to our Oncology Translational Studies Program (OTSP). New as of December 2024, preclinical proposals should also be directed to the OTSP.
- The Program requests that investigators specify how they will support diversity in enrollment, including but not restricted to traditionally underrepresented minorities/ethnic groups.

Please note that IISP proposals competing with or duplicating any registration trial for Nemtabrutinib will not be supported.

The IISP review is a competitive process. Decisions will be made on the basis of scientific/clinical merit and strategic fit, as well as feasibility.

Please be sure to abide by the timelines for this process as outlined below when submitting applications.

Special Note: Diversity & Inclusion and Patient Engagement

We seek to foster diverse and inclusive representation and patient engagement within the individual Areas of Interest for each tumor type. We encourage study proposals across our Program which, in addition to demonstrating scientific merit, also take into consideration the following:

- Outcome disparities in underrepresented populations
- Inclusion of non-academic programs/institutions
- Involvement of under-represented regions or countries

Nemtabrutinib Clinical AOIs for 2025:

- Primary focus of the program in 2025 is on specific lymphomas (DLBCL, Follicular Lymphoma, Marginal Zone Lymphoma, and Waldenstrom's Macroglobulinemia) and cGVHD

- The following lymphomas are of secondary focus in 2025: CLL/SLL, MCL and Richter's Transformation. The program remains interested in innovative concepts for these lymphomas but it is strongly recommended that investigators discuss their concepts with the field or country team before submission.

For both the primary and secondary areas of focus listed above:

  - Combinations with SOC, or other novel therapies (eg, CAR-T, BCL2 inhibitors, polyspecific antibodies, ADCs)

- The following are currently not of interest in 2025 – Primary CNS lymphoma, autoimmune conditions, solid tumors

Note: Potential combination partners for clinical trials should have published toxicity data that can be used to guide trial design and potentially predict expected toxicities. Consideration should be given on whether to include an appropriate safety run-in component.